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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/990,955 | 11/16/2001 | Mitradev Boolell | PCS10382ARTB | 2910 |

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| EXAMINER | |
|---|---|
| KWON, BRIAN YONG S | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/990,955 | BOOLELL, MITRADEV | |
| | Examiner | Art Unit | |
| | Brian S. Kwon | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-7,9,10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,9,10,12 and 13* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



5.00.

## DETAILED ACTION

### *Summary of Action*

I. The objection of the disclosure under 35 USC 132 is not maintained in light of the amendment.

II. The rejection of the claims 1-7 and 9-10 under 35 USC 112, first paragraph, as failing to comply with the written description requirement, is not maintained in light of the amendment.

III. The rejection of the claims 1-7 and 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty et al. (US 6037346 A) and Wilson et al. (US 6403597 B1), and further in view of Bell-Huff et al. (EP 0960621 A2) and Ellis (WO 94/28902) is not maintained in light of the amendment.

IV. Applicant's amendment (now requiring combination treatment with "one or more alpha-adrenergic receptor antagonists, NPY inhibitors, melanocortin enhancers, 5-HT3 or 5-HT4 antagonists, modulators of transporters for noradrenaline, dopamine and/or serotonin or anti-depressants) necessitates a new ground of rejection(s) in this Office Action.

### *Status of Application*

1. By Amendment filed March 07, 2005, claims 1, 8 and 11 have been cancelled; claims 2-3, 7 and 9 have been amended; and claims 12-13 have been newly added. Claims 2-7, 9-10 and 12-13 are currently pending for prosecution on the merits.

### *Response to Arguments*

2. No argument is present in the Applicant's Response filed March 07, 2005.

### *Claim Objections*

3. Claim 13 is objected, as being of improper dependent form. Claim 13 is depending on itself. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2-7, 9-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 6403597 B1).

Wilson teaches the use of a composition comprising type V phosphodiesterase inhibitor (i.e., sildenafil, pyrazolopyrimidinone, zaprinast) in combination with a selective serotonin re-uptake inhibitor (i.e., trazodone) for treating erectile dysfunction including premature ejaculation

via various dosage forms including oral, transmucosal, topical and parenteral, wherein said PED5 inhibitor is given a daily in the rage of approximately 0.1 to 500mg/day (abstract; column 10, line 50 thru column 11, line 45; column 13, lines 7-18; column 14, line 44 thru column 23, line 32; claims 44 and 49).

The teaching of Wilson differs from the claimed invention in the use of PDE 5 inhibitor in "normal erectile function".

Although the reference is silent about said composition in the treatment of premature ejaculation with "normal erectile function" patient, one having ordinary skill in the art would have motivated to apply the claimed composition, with reasonable expectation of success, to treat patients with premature ejaculation regardless of normal erectile function or erectile dysfunction. One having ordinary skill in the art would have known that said composition would be effective in treating premature ejaculation in patients with "normal erectile function" as well as erectile problem patient. The state of the premature ejaculation treatment art does not distinguish between patient with "normal erectile function" and patient with erectile function problem. Rather, the prior art generally teaches that any effective agents for the treatment of premature ejaculation would be effective in treating premature ejaculation regardless of "normal erectile function" or erectile problem. Based on the state of the prior art, differences in "normal erectile function" will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such "normal erectile function" is critical.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share

common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

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